US CUSTOMS SERVICE

LABORATORY ACCREDITATION PROGRAM
COMMODITY GROUP BROCHURE

DRAFT

Organic Materials Including Intermediates & Pharmaceuticals

LABORATORIES AND SCIENTIFIC SERVICES
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CONTENTS

The information provided below should be considered in DRAFT form, as the current regulations are just in the proposal stage. The information provided in this brochure should assist in the process of becoming an accredited laboratory. It is not a substitute for the complete guidelines which are being provided in the Federal Register.

Background

On December 8, 1993, the United States enacted the North American Free Trade Agreement Implementation Act (the Act), which contained provisions pertaining to Customs Modernization and section 613 of Subtitle A to Title VI which amends section 499 of the Tariff Act of 1930. Section 613 of the Act was established to codify existing Customs practices which had evolved to meet the demands of international trade regarding the examination and detention of merchandise: by removing obsolete examination requirements; authorizing the Secretary to designate examination sites; and providing for the collection of duties, fees, and taxes on merchandise not specified in an invoice or entry.

The provisions also codify Customs regulations and administrative guidelines concerning the use of commercial laboratories and gaugers. A new subsection (b) authorizes Customs to set procedures for the accreditation of commercial laboratories and for the approval of commercial gaugers and provide for the suspension and revocation of accreditations and approvals. A reasonable charge for accreditation or reaccreditation may be imposed. This subsection also creates appeal rights for commercial laboratories and gaugers to challenge in the Court of International Trade any order or decision relating to their accreditation or reaccreditation or the assessment of a penalty within 60 days of its issuance. Further, this subsection provides that, (1) in the absence of Customs testing, Customs shall accept analysis and quantity results from the Customs accredited laboratories and gaugers, but does not limit or preclude Customs or any other Federal agency from independently testing, analyzing or quantifying merchandise; (2) testing procedures and methodologies will, unless they reveal information proprietary to Customs, i.e., developed by Customs for enforcement purposes, or provided to Customs in confidence by a copyright, trademark or patent holder, be made available upon request to laboratories and importers or their agents. Testing results will be made available to the importer of record and/or his official representative; and (3) laboratories/gaugers may seek judicial review of any final Customs decision that adversely affects their accreditation/approval, i.e., denial, suspension, or revocation, or that imposes a monetary penalty, by commencing an action within 60 days of such decision in the Court of International Trade.

The regulations implementing the examination of merchandise provision of section 499 are found in part 151 of the Customs Regulations (19 CFR part 151); 151.12 and 151.13 pertains to commercial gaugers and laboratories. Complete text of the regulations can be found in the Federal Register, and it is the responsibility of the commercial laboratory or gauger to follow them. This brochure outlines the procedure, but should not be the sole source for anyone seeking to become an accredited commercial laboratory.

Definitions

1. An "analysis record" is a compilation of all documents which have been generated during the course of analysis of a particular sample which, under normal circumstance, culminates in the issuance of a laboratory report. An analysis record may include, both in paper and electronic form, such documents as worksheets, notes, associated spectra (both spectra of the actual product and standard spectra used for comparison), photographs and microphotographs, and the laboratory report.

2. "Authorized signatories" are individuals who have been approved by Customs to sign laboratory reports issued by Customs-accredited laboratories for Customs purposes. Company and corporate officers are given authorized signatory status at the time of accreditation. Such officers appointed after the initial accreditation becomes effective will become authorized signatories upon successful completion of a background investigation.

3. "Check samples" are samples which have been distributed by Customs to accredited laboratories to test their proficiency in a certain area of accreditation.

4. "Commercial laboratories" are individuals and commercial organizations which analyze merchandise, i.e. to determine its composition and/or characteristics, through laboratory analysis. Commercial laboratories may own and operate commercial gaugers and vice versa; however, gauger approvals are granted separately by Customs under section 151.13.

5. A "Customs-accredited laboratory" is a commercial laboratory, within the United States, that has demonstrated, to the satisfaction of the Director, pursuant to this section, the capability to perform analysis of certain commodities to determine elements relating to the admissibility, quantity, composition, or characteristics of imported merchandise. The specific commodity groups are listed on the last page of this brochure.

Accreditation of Commercial Laboratories, Part 151

Laboratories will be accredited for test procedures within commodity groups. These test procedures are listed in the appropriate Commodity Group Brochures, such as this, and are available from Customs. Laboratories may apply for accreditation in more than one commodity group. At the discretion of the Director, Laboratories and Scientific Services, accreditation may be granted for subgroups of tests within a commodity group or for commodity groups not specifically enumerated. Once accredited, laboratories may apply to add additional tests within a group or other commodity groups.

Customs shall accept, from Customs-accredited laboratories, laboratory reports providing data required for specific Customs purposes. The data must be obtained using methods approved by the Director, Laboratories and Scientific Services. These methods consist of both industry

standard test methods and Customs laboratory methods. While Customs laboratory methods may be obtained through the Director, Laboratories and Scientific Services, methods published by organizations such as ASTM, API, and similar organizations are not available through U.S. Customs. In cases where neither a published commercial method nor a Customs laboratory method is indicated, the commercial laboratory shall use a method of analysis which has been approved for use in Customs-related transactions by the Director, Laboratories and Scientific Services. This approval can be requested in writing during the application process or, any time after a laboratory has been accredited.

Nothing in these regulations shall preclude Customs from sampling and testing merchandise from a shipment which has been sampled at the request of an importer and tested by a Customs-accredited laboratory. In cases where a shipment has been analyzed by both a Customs laboratory and a Customs-accredited laboratory, all Customs actions will be based upon the analysis provided by the Customs laboratory unless the Director, Laboratories and Scientific Services, advises other actions.

Application Procedures

Commercial laboratories seeking accreditation shall send a letter of application to the U.S. Customs Service, Attention: Director, Laboratories and Scientific Services, 1300 Pennsylvania Avenue, N.W., Section 5.5-B, Washington, DC 20229. Applications shall include:

1. The applicant's legal name and the addresses of the principal place of business and any other facilities;

2. Detailed statements of ownership and any partnerships, parent-subsidiary relationships, or affiliations with any other domestic or foreign organizations, including, but not limited to, importers, other commercial laboratories, producers, refiners, Customs brokers, and carriers.

3. A statement of financial condition;

4. If a corporation, a copy of the articles of incorporation and the names of all officers and directors;

5. The names, titles, and qualifications of each person who will be authorized to sign or approve analysis reports on behalf of the commercial laboratory;

6. A complete description of the applicant's facilities, instruments, and equipment;

7. A Continuous Public Gauger Bond as provided for in Customs Directive 3510-04 executed in accordance with Part 113 of the Customs Regulations (19 CFR 113). The

bond need not be obtained until the final stages of the application review process. The applicant will be notified by Customs at the appropriate time to submit the bond to any Customs port office. Limits of liability on the bond will be established by the Customs port office in consultation with the Director, Laboratories and Scientific Services. In order to retain Customs accreditation, the laboratory must maintain its bond, and if necessary, upgrade it if requested to do so by the Customs port;

8. A statement for each commodity group for which accreditation is being sought, primarily:

   a. That all tests on all commodities in a named group can be performed, or

   b. That all tests on the commodities in a group except those indicated can be performed, or

   c. That the listed procedures which are not specifically provided for in the commodity group brochure are being submitted for approval for use;

9. A nonrefundable pre-payment equal to 50 percent of the fixed accreditation fee, as published in the **Federal Register** and **Customs Bulletin**, to cover preliminary processing costs. Further, the applicant agrees to pay Customs within 30 days of notification the associated charges assessed for accreditation, i.e., those charges for actual travel and background investigation costs, and the balance of the fixed accreditation fee.

10. A written agreement to avoid conflict-of-interest situations and to comply with requirements prescribed by Customs.

The accreditation process will include a general review of the applicant's physical plant and management system and specific assessments for each commodity group of application. The overall laboratory accreditation will consist of a review along the lines of the ASTM E 548 Standard Guide for General Criteria Used for Evaluating Laboratory Competence. This review will ascertain the laboratory's ability to manage and control the acquisition of technical data. This review will be performed at the time of initial application and upon reaccreditation at three-year intervals.

The specific accreditation for each commodity group for which accreditation is requested will focus on the laboratory's ability to perform the tests required in that commodity group. This, in particular, will include the qualifications of the technical personnel in this field and the availability of instruments required by the test methods.

Maintenance of accreditation will be on-going and will require the submission of test results on periodic check samples. The criteria for acceptance will be based on the laboratory's ability to produce a work product that will provide accurate technical data that can be used to establish the proper classification of and duty collection for the imported article.

The Director, Laboratories and Scientific Services, shall determine the applicant's competence and independence by use of appropriate techniques, including on-site inspections and background investigations. When Customs evaluation of the applicant is complete, the Director, Laboratories and Scientific Services, shall give notification to the applicant of approval or disapproval. Partial approvals and full disapprovals will include the reasons for these decisions. Final approval decisions will not be made until the applicant has satisfied all bond requirements and has made payment on all required application fees. All notices of approval, reapproval, and the extension of a laboratory's existing accreditations shall be published in the Federal Register and Customs Bulletin.

Laboratories receiving an adverse accreditation determination and wishing to appeal the determination must file an appeal within 30 days to the Director. Within 30 days of the receipt of the appeal, the Director shall make a final determination regarding the appeal and notify the laboratory in writing. If the Director reaffirms the nonselection, again citing specific reasons, then the applicant may choose to either: (I) submit a new application to the Director after waiting 90 days from the date of the Director's last decision; or (ii) file an action with the Court of International Trade, pursuant to chapter 169 of title 28, United States Code, within 60 days after the issuance of the Director's final decision.

Technical and Operational Requirements

To be accredited and to maintain accreditation, a commercial laboratory shall conform to the following:

1. Methods. The Director, Laboratories and Scientific Services, may require laboratories to follow specific methods for designated commodities to meet Customs technical requirements. Alternative methods will be considered on a case by case basis. In the absence of a specific procedure, laboratories shall employ recognized techniques based upon sound scientific principles.

2. Equipment. The laboratory shall be equipped with all of the instruments and equipment needed to conduct the tests for which it is accredited. The laboratory shall ensure that all instruments and equipment are properly calibrated, checked, and maintained.

3. Facilities. The laboratory shall conduct its work in facilities which have adequate space, lighting, and environmental controls to ensure compliance with the conditions prescribed in appropriate test procedures.

4. Personnel. The laboratory shall be staffed with personnel having the necessary professional training, knowledge, and experience for their assigned functions. In general, laboratory staff should have, at a minimum, a bachelor's degree in the sciences or two years related experience in an analytical laboratory.

5. Subcontracting. Laboratories accredited under this program shall not subcontract Customs-related analyses.

6. Record keeping requirements. Accredited laboratories shall maintain records of the type normally kept in the ordinary course of business. In addition, these laboratories shall maintain all records necessary to permit the evaluation and verification of all Customs-related work. All records shall be maintained for a minimum of ten years. Records to be kept shall include:

    1. Analysis record. Refer to the definition on page 4 of this brochure for the contents of the analysis record.

    b. Sample logs. Listing of samples tested for Customs purposes must be readily accessible and have the following: (I) a unique identifying number; (ii) the date when the sample was received or taken; (iii) the identity of the commodity; (iv) the name of the client; and (v) the source of the sample.

    c. Major equipment records of every instrument used in Customs-related work must have the name and type of the instrument, the manufacture's name, the instrument's model and serial numbers, and the details of all major servicing, recalibration, etc.

USCL METHODS FOR ORGANIC MATERIALS INCLUDING INTERMEDIATES & PHARMACEUTICALS

This Commodity Brochure covers commodities of the chemical and allied industries which are listed in Chapters 29, 30, 34, 35, and 38 of the Harmonized Tariff Schedule of the United States (HTSUS). These commodities include, but are not limited to, organic chemicals, biochemicals, chemical mixtures, preparations, pharmaceutical products and miscellaneous chemical products. It is intended to provide guidance in analytical approaches for the analysis of the covered products necessary to ensure proper HTSUS classification. Due to the expansive and often unique analytical requirements of the HTSUS, sometimes specific established analytical methodology may not exist. In these cases you will need to rely on commonly accepted laboratory practices. This can include using another applicable standard method or developing a method of analysis to meet the specific analytical requirements of the instant commodity.

Product terms and definitions found in the HTSUS are frequently different from terms or definitions used commercially. To ensure that proper determinations are made, pertinent HTSUS Section and Chapter notes and the Explanatory Notes to the HTSUS must be relied upon. Occasionally, provisions of the HTSUS and the Explanatory Notes conflict with the procedures found in recognized methods. When this occurs, the provisions of the HTSUS and/or Explanatory Notes must prevail.

Note that the methods, practices and HTSUS can be updated, modified, and sometimes replaced. Therefore, it is important to use the documents that are in effect at the time of importation.

USCL NUMBER	METHOD	TITLE OF METHOD
04-03	AOAC 922.03A	Casein in Milk A. Method I
04-04	AOAC 923.24	Albumin in Milk
04-25	ASTM D 2800	Test Method for Preparation of Methyl Esters from Oils for Determination of Fatty Acid

USCL NUMBER	METHOD	TITLE OF METHOD
04-24	ASTM D 1983	Test Method for Fatty Acid Composition by Gas Chromatography of Methyl Esters
12-01	AOAC 963.22	Methyl Esters of Fatty Acids in Oils and Fats Gas Chromatographic Method (AOAC-IUPAC Method)
29-01	ASTM D 3797	Test Method for Analysis of o-Xylene by Gas Chromatography
29-02	ASTM D 3738	Test Method for Analysis of p-Xylene by Gas Chromatography
29-03	ASTM E 200	Practice for Preparation, Standardization, and Storage of Standard Solutions for Chemical Analysis
29-04	ASTM D 3457	Method for Preparation of Methyl Esters from Fatty Acids for Determination of Fatty Acid Composition by Gas-Liquid Chromatography
29-05	ASTM E 324	Test Method for Relative Initial Final Melting Points and the Melting Point Range of Organic Chemicals
29-06	ASTM E 169	Practices for General Techniques of Ultra-violet Quantitative Analysis
29-07	USP 851	Spectrophotometry & Light Scattering
29-08	ASTM D 2369	Test Method for Volatile Content of Coatings
29-09	USCL Manual	Organic Qualitative Analysis
29-10	ASTM E 682	Practice for Liquid Chromatography Terms and Relationships

USCL NUMBER	METHOD	TITLE OF METHOD
29-11	USCL Manual	Method for Emission Spectrochemical Analysis
30-01	USP 731	Loss on Drying
30-02	USP 733	Loss on Ignition
30-03	USP 726	Electrophoresis
30-04	USCL Manual	Qualitative Analysis for Medicaments & Pharmaceutical Substances
30-05	USP 71	Sterility Tests
30-06	USP 501	Salts of Organic Nitrogenous Bases
30-07	ASTM D 3870	Practice for Establishing Performance Characteristics for Colony Counting Methods in Microbiology
30-08	USP 81	Antibiotics-Microbial Assays
30-09	USP 191	Identification Tests - General
30-10	USP 201	TLC Identification Test
33-06	USP 761	Nuclear Magnetic Resonance
33-07	ASTM E 386	Data Presentation Relating to High Resolution Nuclear Magnetic Resonance (NMR) Spectroscopy
33-08	USP 621	Chromatography
34-01	ASTM D 1331	Test Methods for Surface and Interfacial Tension of Solutions of Surface-Active Agents
34-02	ASTM D 2357	Qualitative Infrared of Surface-Active Agents

USCL NUMBER	METHOD	TITLE OF METHOD
34-03	USCL Manual	Organic Surface-Active Agents: Qualitative Analysis
34-04	ASTM D 2669	Test Method for Apparent Viscosity of Petroleum Waxes
34-05	ASTM D 3954	Test Method for Dropping Point of Waxes
34-06	ASTM D 2358	Method for Separation of Active Ingredients from Surfactants and Syndet Compositions
35-01	USCL Manual	Gelatin Analysis
35-02	USCL Manual	Enzyme Assays
35-03	AOAC 948.21	Jelly Strength of Gelatin
35-04	ASTM D 4689	Specification for Adhesive, Casein-Type
35-05	ASTM D 4800	Guide for Classifying and Specifying Adhesives
35-06	ASTM D 1488	Test Method for Amylaceous Matter in Adhesives
35-07	USCL Manual	Analysis by Microscopy
38-01	ASTM D 3467	Test Method for Carbon Tetrachloride Activity of Activated Carbon
38-02	ASTM D 803	Methods of Testing Tall Oil
38-03	ASTM D 13	Specifications for Spirits of Turpentine
38-04	ASTM D 233	Test Methods for Sampling and Testing of Turpentine
38-05	ASTM D 3009	Test Method for Composition of Turpentine by Gas Chromatography - Modified

USCL NUMBER	METHOD	TITLE OF METHOD
38-06	ASTM D 1131	Methods of Testing Rosin Oils
38-07	ASTM D 3008	Test Method for Resin Acids in Rosin by GLC - Modified
38-08	ASTM D 4951	Determination of Additive Elements in Lubricating Oils by Inductively Coupled Plasma Atomic Emission Spectrometry
38-09	ASTM D 3465	Practice for Purity of Monomeric Plasticizers by Gas Chromatography
38-10	ASTM D 3156	Practice for Rubber - Chromatographic Analysis of Antidegradants (Stabilizers, Antioxidants, and Antiozonants)
38-11	ASTM D 4818	Classification for Rubber Compounding Materials - Vulcanization Accelerators
38-12	ASTM D 2349	Method for Qualitative Determination of Nature of Thinner in Solvent-Type Paints
38-13	ASTM D 4337	Test Methods for Analysis of Linear Detergent Alkylates
39-03	ASTM D 4128	Practice for Identification of Organic Compounds in Water by Combined Gas Chromatography Electron Impact Mass Spectrometry
39-15	ASTM D 2257	Test Method for Extractable Matter in Textiles
44-03	ASTM D 3860	Practice for Determination of Adsorptive Capacity of Activated Carbon by Aqueous Phase Isotherm Technique
44-04	ASTM E 355	Recommended Practice for Gas Chromatography Terms and Relationships

USCL NUMBER	METHOD	TITLE OF METHOD
50-09	ASTM E 168	Recommended Practices for General Techniques of Infrared Quantitative Analysis
50-10	ASTM E 334	Practice for General Techniques of Infrared Microanalysis
50-11	ASTM E 1252	Practice for General Techniques for Qualitative Infrared Analysis

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Commodity Group Brochures

- Dairy and Chocolate Products (HTSUS Chapters 4, 18, and 21)
- Food and Food Products (HTSUS Chapters 7-12, 15, 16, and 19-21)
- Botanical Identification (HTSUS Chapters 14, 44, 45 and 46)
- Sugar, Sugar Syrups and Confectionery (HTSUS Chapter 17)
- Spirituous Beverages (HTSUS Chapter 22)
- Building Stone, Ceramics, Glassware and Other Mineral Substances (HTSUS Chapters 25, 68, 69 and 70)
- Inorganic Materials, including Inorganic Compounds and Ores (HTSUS Chapters 26, 28, 31, and 36-38)
- Petroleum and Petroleum Products (HTSUS Chapters 27 and 29)
- Organic Materials, including Intermediates and Pharmaceuticals (HTSUS Chapters 29, 30, 34, 35, and 38)
- Rubber, Plastics, Polymers, Pigments and Paints (HTSUS Chapters 32 39 & 40)
- Essential Oils and Perfumes (HTSUS Chapter 33)
- Leather (HTSUS Chapters 41 and 42)
- Paper and Paper Products (HTSUS Chapters 47, 48, 49)
- Textile and Related Products (HTSUS Chapters 50-67)
- Metals and Alloys (HTSUS Chapters 72-83)